510(k) Summary
AutoBand Ligator

1. Company Identification

EndoChoice, Inc.
11800 Wills Road
Alpharetta, GA 30009
Telephone (678) 708 4743
FAX (678) 567 8218
Establishment Registration: 300759133

AUG 2 3 2013

2. Contact Person

Daniel Hoefer
Regulatory Affairs Manager

3. Device Name

Commercial name: *AutoBand Multiple Band Ligator*
Classification name: Hemorrhoidal Ligator

4. Device Classification

Product Code: MND
Regulation Number: 876.4400
Class: II

5. Intended Use

The AutoBand Multiple Band Ligator is used to band esophageal varices or hemorrhoids in the colon. The device is intended for single use only.

6. Device Description

The AutoBand Multiple Band Ligator device consists of the applicator unit (including the band barrel, handle, activation wheel, wheel grip, beaded string, interior stainless steel trigger wire, and fixation arm), a fixation strap, and the ligation bands that are mounted on the barrel.

The device is intended for single use and is supplied non-sterile. The ligation bands are intended for endoscopic placement in the esophagus or colon, with the trigger wire introduced through the biopsy port of the endoscope. Each AutoBand barrel is pre-loaded with seven bands. Models are manufactured for compatibility with either gastroscopes or colonoscopes. AutoBand model designations also are differentiated based on compatibility with different endoscope manufacturers.

7. Substantial Equivalence

The device submitted for review is a modification of the Auto-Band Ligator (K083556, Scandimed International).

Changes to the device include a modification in materials specification of the ligation bands. The unmodified bands are composed of natural latex rubber, while in the modified device they are synthetic Polyisoprene. In addition, the modified device includes minor design changes to the beaded deployment strand and the wire locking assembly arm; each of these mechanical changes is intended to improve ligation band deployment performance.

As a result of the modification to the band material, the labeling of the device no longer includes a caution statement that the device may cause allergic reactions due to the presence of natural latex rubber. The labeling now includes the statement "Not made with natural latex rubber."

The modified device is identical in terms of intended use, operating principle, performance, technology, energy used, and packaging.

See Table 1 below.

SUBSTANTIAL EQUIVALENCE COMPARISON WITH PREDICATE DEVICE

Characteristic	Auto-Band Ligator (Latex)	AutoBand Ligator (Non-latex)
510(k) number	K083556	Pending
Indications for Use	The Auto-Band Ligator is used to band esophageal varices or hemorrhoids in the colon.	The AutoBand Ligator is used to band esophageal varices or hemorrhoids in the colon.
Operation	Varices are aspirated into the band barrel. Once in the correct position, the band is then deployed over the varix (the elastic band will assure that blood flow into the varix is stopped).	Varices are aspirated into the band barrel. Once in the correct position, the band is then deployed over the varix (the elastic band will assure that blood flow into the varix is stopped).
Ligator Wheel design	• Automatic Reverse • The Ligator wheel is designed with start and stop positions to ensure that no more than one band is deployed at a time. When the band is deployed, the wheel head will go automatically to the start position • The Ligator wheel has a locking arm so that the trigger cord is held in the correct position to facilitate fully controlled deployment of the band.	• Automatic Reverse • The Ligator wheel is designed with start and stop positions to ensure that no more than one band is deployed at a time. When the band is deployed, the wheel head will go automatically to the start position • The Ligator wheel has a locking arm so that the trigger cord is held in the correct position to facilitate fully controlled deployment of the band.
Band Barrel design	• The transparent band barrel is loaded with the bands next to each other • Only one cord in the band barrel is used to deploy the bands • The band deployment cord is supplied with small glass pearl to ensure	• The transparent band barrel is loaded with the bands next to each other • Only one cord in the band barrel is used to deploy the bands • The band deployment cord is supplied with small glass beads to ensure

	correct and effective deployment of the bands.	correct and effective deployment of the bands.
Ligator Body design	• Mounting of the wheel is on a flexible arm, which allows the device to be firmly fixed on the scope; this ensures a high level of stability and precision during the procedure	• Mounting of the wheel is on a flexible arm, which allows the device to be firmly fixed on the scope; this ensures a high level of stability and precision during the procedure
Number of bands	5, 6, 7, 8, or 10	Same
Materials	Band Barrel: Acrylic Cord: Nylon Band: Natural Latex Rubber Pearl: Glass Ligator Body: Polycarbonate Loading wire: Stainless Steel	Band Barrel: Acrylic Cord: Nylon Band: Synthetic Polyisoprene Bead: Glass Ligator Body: Polycarbonate Loading wire: Stainless Steel
Patient Contact	Ligation Bands are surface devices contacting mucosal membranes for prolonged duration.	Ligation Bands are surface devices contacting mucosal membranes for prolonged duration.
Packaging	PET (Polyethylene Terephthalate) Blister Pack	PETG (Polyethylene Terephthalate Glycol) Blister Pack
Biocompatibility of Band	Ligation Bands material is cytotoxic when tested in accordance with ISO 10993-5:1999	Tested for sensitization, irritation, and cytotoxicity. Ligation Band material is cytotoxic when tested in accordance with ISO 10993-5:1999 See Vol_014 Biocompatibility
Sterilization	Single Use Non-Sterile	Single Use Non-Sterile

TABLE 1

8. Non-clinical testing

The modified device has undergone both bench testing of performance and laboratory biocompatibility testing for Irritation, Sensitization, Cytotoxicity, and System toxicity, in accordance with ISO 10993-1. In addition, the materials in the synthetic Polyisoprene bands were tested in accordance with the ELISA inhibition assay (ASTM D6499-07) and the Allergen ELISA (ASTM D74727-08), with result showing that allergens clinically relevant to latex allergy are not present to within detection limits.

Other design changes resulted in completion of non-clinical functional verification testing.

9. Conclusion

The modified AutoBand Ligator is substantially equivalent to the unmodified predicate device listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 23, 2013

EndoChoice, Inc.
% Daniel Hoefer
Regulatory Affairs Manager
11810 Wills Road
Alpharetta, GA 30009

Re: K132535
Trade/Device Name: AutoBand Ligator
Regulation Number: 21 CFR§ 876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: II
Product Code: MND
Dated: August 9, 2013
Received: August 13, 2013

Dear Daniel Hoefer,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.
You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132535

Device Name: AutoBand Ligator

Indications for Use:

The AutoBand Ligator is used to band esophageal varices or hemorrhoids in the colon.

Prescription Use __X__ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K132535